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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,756	07/13/2001	William V. Curran	8067-094-999	3899

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/904,756	Applicant(s) CURRAN ET AL.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- Th **MAILING DATE** of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 22, 24-26 and 28-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 11-20, 22, 24-26, 28-31 and 34-42 is/are rejected.
- 7) ☒ Claim(s) 5-10, 32 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The amendment filed August 28, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment to page 34, line 1, of the specification inserting the application serial number is new matter because the instant specification as originally filed did not include a reasonably precise identification of application serial no. 09/948,374 to permit its insertion into the specification. See MPEP 608.01(p)(I)(A) and *In re Fouche*, 169 USPQ 429 (CCPA 1971) cited therein. Note that there are numerous applications by the instant inventors which involve antibiotics. In addition to the application mentioned above, there is parent application 09/760,328; copending applications 09/948,374 and 10/321,827; and unrelated applications 08/420,955, 07/403,232, and 10/142,303.

Applicant is required to cancel the new matter in the reply to this Office Action.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 11-20, 22, 24-26, 28-31, and 34-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the negative claim limitation "wherein said core cyclic peptide or core antibiotic is not... polymyxin". The original disclosure of the invention does not refer to polymyxin, and silence in the specification

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does not constitute support for a negative claim limitation. See *Ex parte Grasselli*, 231 USPQ 393, *aff'd on reconsideration* 231 USPQ 395 (Bd. App. 1983). Applicants have not indicated where the original disclosure of the invention supports the new claim limitation.

3. Claims 4-20, 22, 24-26, 28-36, and 38 are objected to because of the following informalities: At claim 4, page 4 of the amendment, line 1, “-co-“ should be changed back to “-CO-“. At claim 4, page 4, lines 2 and 3, the numeral “2” after “SO” should be changed back to a subscript. At claim 4, page 4, line 18, the numeral “3” after “N” should be changed back to a subscript. At claim 29, line 3, the numeral “4” after “S” should be changed back to a superscript. At claim 38, line 2, “a” should be changed to “an”. Appropriate correction is required.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-4, 12, 30, 31, 34-38, and 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 98/00173. The WO Patent Application '173 teaches a drug, which can be an antibiotic, conjugated through a sulfonamide group to an optionally substituted phenyl or 5- or 6-membered heterocyclic ring. The drug can be reacted with the appropriate sulfonyl chloride in order to form the final conjugated product. See, e.g., page 7, line 35 - page 8, line 5; page 14, line 34 - page 15, line 10; page 23, lines 9-12; and page 33, line 1.

6. Applicant's arguments filed August 28, 2003 have been fully considered but they are not persuasive.

The terminal disclaimer over U.S. Patent No. 6,511,962 filed August 28, 2003 has been approved. The provisional obviousness-type double patenting rejection over copending

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application 09/904,352 is withdrawn in view of the amendments to the instant claims excluding laspartomycin as a core cyclic peptide or core antibiotic.

The anticipation rejection over Bouchaudon et al (U.S. Patent No. 3,817,973) is withdrawn in view of the new claim limitation excluding polymyxin as the core cyclic peptide or core antibiotic. Should this limitation be deleted in response to the above rejection under 35 U.S.C. 112, first paragraph, the examiner will consider the propriety of re-instituting this rejection.

The anticipation rejection over the WO Patent Application 98/00173 is maintained. The WO Patent Application '173 explicitly names antibiotics (see, e.g., page 15, line 15, and claim 4) and explicitly names actinomycin (see, e.g., page 33, line 1, and claim 5). The only context in which it names these compounds is in the context of conjugating these compounds through sulfonamide groups to an optionally substituted phenyl or 5- or 6-membered heterocyclic ring (see, e.g., page 7, line 35 - page 8, line 5). The optionally substituted phenyl or 5- or 6-membered heterocyclic rings are lipophilic moieties. Actinomycin is an antibiotic - see, e.g., Cooper (U.S. Patent No. 4,557,934) at column 15, lines 7-19, and Shih et al (U.S. Patent No. 5,057,313) at claim 19.

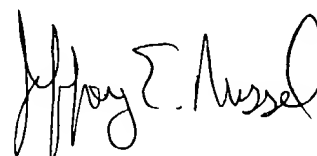
7. Claims 5-10, 32, and 33 would be allowable if rewritten to overcome the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

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